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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,393	02/27/2004	Tony Mikaer Wahlroos	108306-00024	5309

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EXAMINER

WORLEY, CATHY KINGDON

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/787,393	Applicant(s) WAHLROOS ET AL.	
	Examiner Cathy K. Worley	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 12, 15, 17, and 22, drawn to a method for increasing the content of one or more selected amino acids in a selected tissue or organ of a plant, wherein said selected tissue or organ is a cell wall or a cell membrane, classified in class 800, subclass 278, for example.
- II. Claims 13 and 16, drawn to a method for increasing the content of one or more selected amino acids in a selected tissue or organ of a plant, wherein said selected tissue or organ is an oil body, classified in class 435, subclass 468, for example.

INVENTIONS I AND II ARE LINKED BY CLAIMS 1-11, 14, 18-21, AND 23-25.

- III. Claims 26-42 and 45-51, drawn to a recombinant nucleotide sequence construct for increasing the content of one or more selected amino acids in a selected tissue or organ of a plant, classified in class 536, subclass 23.4, for example.
- IV. Claims 43-44, drawn to a method for producing a composition comprising in plant material an amino acid-enriched carrier protein

having a polyamino acid extension, classified in class 426, subclass 635, for example.

- V. Claim 52, drawn to a composition comprising in plant material an amino acid-enriched carrier protein having a polyamino extension, classified in class 426, subclass 615, for example.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I can be practiced without using the invention of group II. For example, the invention of group I can be practiced using a protein that is targeted to the cell wall without being targeted to an oil body. Similarly, the invention of group II can be practiced using a protein that is targeted to an oil body without being targeted to a cell wall.

A search for the invention of group I will require searching the literature for methods comprising the use of fusion proteins that are targeted to cell walls. A search for the invention of group II will require searching the literature for methods comprising the use of fusion proteins that are targeting to oil bodies. These searches are not coextensive, and therefore it would constitute an undue burden to examine these inventions together. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions III and I-II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids of invention III could be used in a different method, such as for *in vitro* transcription/translation in a wheat germ extract. The plants of invention III could be used for control extracts containing reporter proteins, for example.

A search for the methods of inventions I-II will require searching the literature for methods of increasing amino acid content. A search for the products of invention III will require searching the nucleic acid databases for chimeric constructs with the recited elements and searching the literature for plants comprising said constructs. These searches are not coextensive, and therefore it would constitute an undue burden to examine the inventions together. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

The inventions of groups I-II are patentably distinct from the inventions of groups IV-V. The methods of groups I-II can be practiced without using the method of group IV or the composition of group V. For example, the methods of groups I-II

do not require the composition of group V and extracts of the plants produced by the methods of groups I-II do not necessarily comprise the composition recited in groups IV or V.

A search for the methods of group I-II will require searching the literature for methods of increasing the amino acid content of selected plant tissue. A search for the method of group IV and composition of group V will require searching the literature for compositions comprising plant material and for oil cakes with the recited amino acid ratio. These searches are not coextensive, and therefore it would constitute an undue burden to examine these inventions together. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

The invention of group III is patentably distinct from the inventions of groups IV-V. The nucleic acids of group III can be used for a substantially different purpose, for example, they can be used for *in vitro* transcription/translation in a wheat germ extract. The plants of group III can be used without producing an oil cake or a composition, such as those recited in groups IV-V.

A search for the invention of group III will require searching the nucleic acid databases for chimeric constructs with the recited elements and searching the literature for plants comprising said constructs. A search for the method of group IV and composition of group V will require searching the literature for compositions

comprising plant material and for oil cakes with the recited amino acid ratio. These searches are not coextensive, and therefore it would constitute an undue burden to examine these inventions together. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention V could be made by spiking a plant material with an exogenously made recombinant protein, for example, which is a materially different process than the process of invention IV.

A search for the method of invention IV will require searching the literature for methods of increasing amino acid content at least two-fold and method of making feed utilizing oil cakes. A search for the product of invention V will require searching the literature for compositions comprising plant material and fusion proteins with enriched amino acid content. These searches are not coextensive, and therefore it would constitute an undue burden to examine these inventions together. Because these inventions are independent or distinct for the reasons given above

and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Claims 1-11, 14, 18-21, and 23-25 link the inventions of group I and group II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-11, 14, 18-21, and 23-25. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant applications. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

The examiner has required restriction between product (groups III and V) and process (groups I-II and IV) claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn

process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of

the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

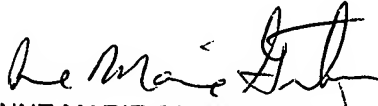
claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CKW
July 3, 2006


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER